ADVANCED MEDICAL STRATEGIES
PHYSICIANS. TAKING CARE OF BUSINESS.

February 12, 2015

Upon request of VUP a medical opinion regarding the treatment provided was conducted on the above patient. Our findings are documented below:

Clinical Summary:

At the time of treatment, the patient was a 56-year-old female, who presented to FH for a right total knee arthroplasty on 12/30/2013. She had a past medical history of hypertension, type 2 diabetes mellitus, diverticulitis, hypothyroidism, hyperlipidemia, osteoarthrosis and degenerative joint disease of the right knee. She had no known drug allergies. Pre-operatively, her medication regimen included Delzicol, Flexeril, folic acid, glucosamine, chondroitin, Lasix, levothyroxine, Lipitor, lisinopril, metformin, fish oil, calcium and vitamin D, vitamin B1, and vitamin E. Her pre-operative lab work was essentially unremarkable. The right total knee arthroplasty took place on 12/30/2013 under epidural anesthesia with MAC (monitored anesthesia care). The orthopedic surgeon of record was JS, M.D. The anesthesia provider was GT, CRNA (certified registered nurse anesthetist). The intra-operative course was uneventful. The epidural placement occurred at 1340 (1:20 p.m.) and was noted to be placed at the L3 to 4 level (lumbar) atraumatically, without the presence of CSF (cerebrospinal fluid), blood, or paresthesias. The patient was taken to the PACU (post-anesthesia care unit) for an uneventful recovery period at 1545 (3:45 p.m.). In PACU, an epidural infusion was begun with ropivacaine and fentanyl at 15 mL/hr (milliliters per hour). The PACU records indicate that the patient was able to move both lower extremities at this time. Her postoperative care continued on 12/30/2013 until 1/1/2014.

On 12/30/2013 at 1600 (4:00 p.m.), an order was placed by Dr. S to administer enoxaparin 40 mg (milligrams) SQ (subcutaneously) daily. There is a clear order comment on the medication administration record: "Warning to RNs (registered nurses): Do not give if patient has an intrathecal or epidural catheter. Do not give within 12 hours before the insertion of an intrathecal or epidural catheter or within two hours after its removal."

The nursing notes clearly document on multiple occasions that the patient was able to move both lower extremities according to the neurologic checks every four hours subsequent to the placement of the epidural catheter intraoperatively. Upon her arrival to the floor, the patient had full sensation to all extremities and only mild weakness in the right leg. The assessment of the epidural site indicated no excessive drainage or bloody discharge.

On 12/31/2013 at 0917 (9:17 a.m.), according to the medication administration record, SP documented the administration of enoxaparin 40mg SQ to the patient in the right abdomen. The same warning was also on the MAR (medication administration record) at this time. The patient had the epidural catheter in place at this time.

According to medical records, the epidural catheter was removed on 12/31/2013 at 2215 (10:15 p.m.) with the tip intact. At this time, the nurses also noted the patient to be very drowsy and

not making sense with her conversation. At 0020 (12:20 a.m.) on 1/1/2014, the patient begins to complain of numbness around her abdomen. This is after the epidural has been stopped. The anesthesiologist on call was JC and he was notified at 0040 (12:20 a.m.) by the nurse of the patient's change in status. It did not appear that he examined the patient personally, and instructed the nurse to continue monitoring because "it is the epidural wearing off". The nurse checks the patient at 0200 (2:00 a.m.) and documents that she is sleeping and comfortable. At 0400 (4:00 a.m.), the patient continues to have abdominal numbness. At 0800 (8:00 a.m.), a CNA (certified nursing assistant) calls for help because the patient cannot hold herself up and appears floppy. The patient now says she cannot feel her legs. The nurse does further neurologic testing and confirms that the patient has decreased sensation in her legs and up to her breast.

At 08:15 a.m., JC was once again notified of the situation. He states he will call the CRNA, GT. At 08:20 a.m., Dr. P who is the on call anesthesiologist was called by the nurse, but was unable to be reached. At 08:45 a.m., Dr. S called to order a stat MRI (magnetic resonance imaging) of the lumbar spine, and the radiology department was notified. Apparently, the radiology department would not be able to perform the test for one hour until the staff came into the hospital. A decision was then made by Dr. P to transfer the patient to another hospital for a higher level of care. The patient left FH at 09:35 a.m. when the transport ambulance arrived.

An MRI of the spine was performed on 1/3/14 at The Medical Center which showed "no evidence of dural AV (arteriovenous) fistula or other arteriovenous malformation from T2 to L3 (thoracic to lumbar)". However, the working diagnosis for this case was an epidural hematoma and resulting paralysis.

The question at hand is whether the treatment during the course of her care caused the ensuing epidural hematoma which caused her paralysis.

Questions:

The claimant had a total knee replacement (right leg). She was given an epidural and became paralyzed. The carrier and reinsurer would like to confirm that there is nothing in the treatment that caused this. Was there any deviation from standard of care during the admission?

Conclusions*:

Yes, there was a deviation from the standard of care during this patient's admission. There were two issues that deviated from standard of care. The first was the administration of enoxaparin to a patient with an epidural catheter in place. The second issue involves the delay in recognition of the symptoms of the epidural hematoma, because early recognition could prevent permanent paralysis if treated appropriately.

The clinical decision to perform this surgery with epidural anesthesia has many benefits including improved postoperative pain management. In addition, this patient is a high risk for developing a deep vein thrombosis (DVT) and therefore needs some form of DVT prophylaxis in the postoperative period. This is the reason that the surgeon ordered enoxaparin. However, in the setting where an epidural catheter was placed and infusing, the timing of administration of enoxaparin needs to very well-coordinated with the entire hospital care team.

Even from the hospital's pharmacy warnings on the medication administration record, the patient should not have received enoxaparin (a blood thinner) while she concurrently had an epidural catheter in place due to concern of developing a spinal hematoma. The standard of care is to avoid administration of prophylactic anticoagulants while an epidural catheter is in place.

The FDA (Food and Drug Administration) released a recommendation on November 6, 2013 regarding the risk of spinal column bleeding and paralysis in patients receiving low molecular weight heparins (e.g. Enoxaparin). In this recommendation, the focus is specifically on the timing of spinal catheter placement and removal in patients receiving anticoagulant medications. They further specify that these anticoagulants should be delayed for at least 12 hours after the placement of the catheter. In addition, they recommend not administering the medication until at least four hours after the catheter is removed.

The statement also reads "healthcare professionals and institutions involved in performing spinal/epidural anesthesia or spinal punctures should determine, as part of a pre-procedure checklist, whether a patient is receiving anticoagulants and identify the appropriate timing of enoxaparin or other anticoagulant dosing in relation to catheter placement/removal."

In addition, the recommendation reads "if signs or symptoms of spinal hematoma are suspected, urgent diagnosis and treatment including spinal cord decompression should be initiated."

The recommendations of The New York School of Regional Anesthesia (NYSORA) specifically address the issue as well. In regards to low molecular weight heparin (e.g. enoxaparin), the recommendation is to postpone its administration until more than two hours after the epidural catheter is removed.

In this case, the anticoagulant was administered to the patient while she still had the epidural catheter in place which deviates from the standard of care.

In regards to the second deviation in care, a high index of suspicion should always be present in any patient who has received spinal or epidural anesthesia. This is the reason why the patient receives ongoing management from the anesthesia providers during this time period.

In this case, the patient began to display symptoms of the spinal cord hematoma on 1/1/2014 at 0020 (per the record). The sequence of events by her care team delayed the diagnosis and treatment until at least 0935, if not longer. According to "Regional Anesthesia: The Requisites in Anesthesiology", "rapid diagnosis and treatment of an epidural hematoma is crucial, as full or partial neurologic recovery is less likely after eight hours have elapsed between the initial onset of symptoms and decompressive laminectomy."

Per this tenet, if the hematoma can be recognized quickly and surgically decompressed, it is possible to have some neurologic recovery and avoid permanent paralysis. However, with this patient, her initial symptoms were misdiagnosed as the epidural wearing off. According to the medical records, the nurse's description to JC at 0020 actually describes an epidural block that was increasing in intensity compared to the previously documented neurologic exams. The patient had never previously had any abdominal numbness. This was clearly an indication of change from her previous level of anesthetic/analgesia from the epidural. It is at this time when the patient first shows any signs of the epidural hematoma. I believe when the nurse called the

anesthesia provider with this information, the patient should have been personally examined by the anesthesia provider to verify the level of the epidural block and perhaps this would have resulted in earlier recognition of the epidural hematoma.

The patient continued to show worsening of the symptoms as the morning wore on. Unfortunately, it was not until 0800 when recognition of the hematoma took place by Dr. S who then proceeded to order the correct testing to confirm the diagnosis. By the time the patient received the appropriate sequence of care, the eight hour window had already elapsed and therefore the resulting permanent paralysis was inevitable.

This case demonstrates a deviation of care for the aforementioned reasons. Her paralysis is an unfortunate result of poor communication between multiple health care providers and the lack of a fail- safe procedure between pharmacy, nursing, and physicians prior to the administration of DVT prophylaxis anticoagulation in the setting of a patient who has an epidural catheter.

Reference(s):

1. U.S. Food and Drug Administration Drug Safety Communications. Updated recommendations to decrease risk of spinal column bleeding and paralysis in patients on low molecular weight heparins. November 6, 2013.

2. Benzon Honorio T. Regional Anesthesia in the Anticoagulated Patient. The New York School of Regional Anesthesia. September 20, 2013.

3. Horlocker Terese, Wedel Denise et al. Regional anesthesia in the patient receiving antithrombotic or thrombolytic therapy: American Society of Regional Anesthesia and Pain Medicine evidence-based guidelines (Third edition). Regional Anesthesia & Pain Medicine. January/February 2010-Volume 35, Issue 1, pp64-101.

4. Hines Roberta Ed. Regional Anesthesia: The Requisites in Anesthesiology. Elsevier Mosby. 2004. pp 151-154.

Reviewer's Credentials

Is board certified in anesthesiology with an active practice. Currently serves as attending anesthesiologist at a regional medical center. Is on the medical performance improvement committee of the medical center. Holds position of adjunct assistant clinical professor at a school of medicine. Is active in professional societies.

**The conclusions in this report may be modified or updated if additional historical or analytical data becomes available. The recommendations noted are made to a reasonable degree of medical certainty. These opinions are based on the medical records and information submitted to AMS for review, Physician/clinician contractors also consider published scientific medical evidence and other relevant information such as that available through federal government agencies, institutes, and professional associations. Advanced Medical Strategies, LLC. assumes no liability for the opinions. The client authorizing this case review agrees to hold AMS harmless for any and all claims which may arise as a result of this case review. This opinion is not intended to be final interpretation of plan/policy language or determination of benefits or exclusions. Adjudication of the claim remains solely the client's responsibility.*

Stacy M. Borans, MD
Chief Medical Officer
Advanced Medical Strategies
781-224-9711 Ext. 101
stacy.borans@mdstrat.com